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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,712	12/05/2003	Thomas Leon	152-55CON	3997

7590 11/24/2004  
Galgano & Burke  
Suite 35  
300 Rabro Drive  
Hauppauge, NY 11788

EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/730,712

Applicant(s)

LEON ET AL.

Examiner

Neil Levy

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/27/04
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-72, 74-80 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☒ Claim(s) 70 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1616

The abstract is 2 paragraphs; it must be one, please amend.

Applicant's election without traverse of Group 6 in the reply filed on 10/28/04 is acknowledged.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-72, 74, 75, 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyes et al WO 89/10740.

Pliable films, in this case with anesthetic active, are adhered to oral mucosa, of the instant unspecified animal. An insert device, otherwise unspecified in instant claim language, is used as a liner (P. 1), paragraph 3 and 4). Binders are PVP (P.3, top), lubricants, Glycerol, and solvent water/ethanol (P. 53<sup>rd</sup> paragraph). Flavorants include sorbital (p.3, 2<sup>nd</sup> paragraph). Films are adhered to oral cavity-teeth and gum (p.7, top).

Claims 70, 74, 76, 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Barbadian et al 4713239.

*Antinginal*  
*Antinational*  
N Antinational films, of polymer binder, fat lubricant (Summary) are adhered to mouth mucosa of the instant unspecified animal patients. Solvents are used (col. 15, top), Example 1, alcohol). Water is no more than 10%.

Claims 70-72, 74, 76-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Britton et al EP 0643963.

The instant animal is not specified. Britton exemplified Rat (p.9). The instant claims are not time-dependent; the device and insertion into Buccal cavity, ~~and is~~ of any shape; soft, pliable enough to adhere to Mucosa (p.3, bottom-line 11, p. 4) p. 10, line 55) permitting therapeutic delivery as device dissolves. Flexibility, dissolution time are a function of the polymer ( the instant binder) and active, and ratio of amounts thereof (p. 4, lines 42-44). Solvent ~~is~~ at lines 49-51. Added components include plasticizers, surfactants, and wetting agents (p. 5, lines 50-51) the instant unspecified lubricants - water content is 5% (line 35, p.7). Alternatively, benzyl alcohol is solvent, water, lubricant (example 17). Treatment was exemplified in ovariectomized rats-devices, buccally delivered, were effective at 1-2 hours (table II). The use of insert devices is described in general-a digit or applicator (p.4, 2<sup>nd</sup> paragraph), thus within the purview of the applicator to apply as is consistent with safe administration, to the Mucosal area of preference of the patient of concern. Moisture is 5% (P. 7, line 35).

Claims 70-72, 74, 76-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Acharya-5110605.

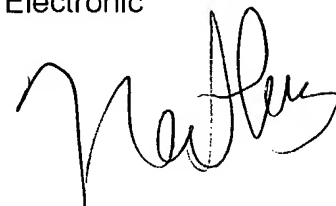
Animals are given therapeutic doses at effective amounts (col. 5, lines 9-28), in a bioadhesive Mucosal delivered device, non-toxic to animals (col. 2, lines 29-32, 49-68), for treating a Malady (col. 3, lines 22-28, 32 line 7, col. 4) including foot and mouth disease, and low growth rate, with vaccine and bovine growth. However, Binders, emulsifiers, dispersants are encompassed (col. 4, lines 55-57), in the film or laminate (line 66). Solvent system for the binder is shown at col. 7, lines 30-61, added lubricant at col. 8, lines 22-24. Delivery to buccal Mucosa may be with forceps (col. 10, top).

The device sticks to the buccal cavity (col. 9, lines 37-400) and provides medicinal treatment to the animal (col. 10, line 16). Form includes discs (col. 10, lines 50-51). Acharya does not make issue of "pliable" film suitable for oral delivery. However, since the components are those instantly claimed, and the Acharya discs adhere to Mycosa, they must be sufficiently pliable, they are suitable for oral delivery. NO moisture need be added, so prior to use, would be less than 15%, under normal humidity, temperature, pressure conditions; and would be minimal in dry environments, thus meeting the instant 4.5-5.5%.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NEIL S. LEVY  
PRIMARY EXAMINER